

## **REMARKS**

Reconsideration and withdrawal of the rejections of the application are requested in view of the amendments and remarks presented herein, which place the application into condition for allowance. The Examiner is thanked for courtesies extended during the Interview of March 1, 2006 and for his assistance since that time.

### **I. STATUS OF CLAIMS AND FORMAL MATTERS**

Claims 2, 4-9, 12-21, 28, 34, 35, 38, 41 and 42 are pending. Claims 14-16 are allowable. Claim 2 is amended as discussed during the March 1 Interview and as indicated on page 5 of the Office Action. Claims 21 and 28 are amended and claims 42 and 43 are added to address the objections under 37 CFR § 1.75(c). No new matter is added.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art, and that these claims are and were in full compliance with the requirements of 35 U.S.C. § 112. The amendments of and additions to the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Furthermore, it is explicitly stated that these amendments should not give rise to any estoppel, as they are not narrowing amendments.

### **II. THE REJECTION UNDER 35 U.S.C. § 112, 1<sup>ST</sup> PARAGRAPH, IS OVERCOME**

Claim 17 was rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. The rejection is traversed.

The Office Action states that the antibodies cAB-Lys3 and V86 are required to practice the invention of claim 17. The Office Action further notes that these elements must be (1) known and readily available to the public or (2) obtainable by a repeatable method set forth in the specification.

Section 2404.01 of the MPEP states that a biological deposit is not necessary if the material is "known and readily available." Indicia include "commercial availability, references to the biological material in printed publications, declaration of accessibility by those working in the field, evidence of predictable isolation techniques, or an existing deposit." MPEP Section

2404.02 says that a deposit is not necessary if the biological materials can be made or isolated without undue experimentation.

Evidence that both of these antibodies are known and readily available can be found in the abundance of articles in the literature that use them. For example, a PubMed search for “cAb-Lys3” reveals eight references and a PubMed search for “V86” reveals fourteen references. A search of the Delphion database for U.S. patents, published U.S. patent applications and PCT applications containing “cAb-Lys3” returned 17 matches. A search of the Delphion database for U.S. patents, published U.S. patent applications and PCT applications containing “V86” returned 267 matches. Predictable isolation techniques are taught in several of these references. Therefore there is evidence under Section 2404.01 that these materials are known and readily available.

In addition, both of these antibodies can be made or isolated without undue experimentation. cAb-Lys3 is an antibody from camel serum, and its isolation is taught in detail in WO 96/34103, published October 31, 1996, prior to the earliest priority date of the present application. US 2003/0088074 (U.S.S.N. 10/154,971; “the ‘971 application”) claims priority to WO 96/34103 and contains the same disclosure. No enablement rejections have been made against the claims of the ‘971 application, providing further evidence that no undue experimentation would be encountered in making or isolating cAb-Lys3.

V86 was isolated from a human melanoma cells and is described and claimed in U.S. Patent No. 6,140,470 (“the ‘470 patent”) as SEQ ID NO: 32. It is assumed that a deposit of V86 was made under the terms of the Budapest Treaty in connection with the ‘470 patent, and that information should be readily available in Patent Office records. Even if a deposit was not made to satisfy Section 2404.01, there must be no undue experimentation in making or isolating V86, or the ‘470 patent would not be enabled. The teachings of the ‘470 patent were available at the earliest priority date of the present application in WO 97/02479, published January 23, 1997, of which the ‘470 patent is the national stage.

The Examiner is reminded of MPEP 2164.05(a), which states that “[t]he specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well-known to those skilled and already available to the public.” *In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991). Therefore, no teaching of the production and isolation of cAb-Lys3 or V86 is necessary in the present application, as the skilled artisan could already make or isolate both

antibodies without undue experimentation at the time the present application was filed. Therefore, Section 2404.02 is satisfied for both cAb-Lys3 and V86 and no biological deposit is required.

In view of the foregoing, reconsideration and withdrawal of the enablement rejection are requested.

**III. THE ART REJECTIONS UNDER 35 U.S.C. §§ 102 & 103 ARE OVERCOME**

Claims 2, 7-9, 12, 13, 20, 21, 28, 34, 35 and 38 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Peach *et al.* Claims 2, 4-6, 18 and 19 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Peach *et al.* in view of Koide. The Examiner has indicated that the amendment to claim 2 made herein would obviate this rejection. Therefore, reconsideration and withdrawal of the anticipation and obviousness rejections are requested.

**CONCLUSION**

Applicants assume that the application is in condition for allowance. If there are any further impediments to allowance of the pending claims that might be resolved telephonically, the Examiner is requested to contact the undersigned, in an attempt to avoid further delays in prosecution. Otherwise, the undersigned looks forward to receive a Notice of Allowance at an early date.

Respectfully submitted,

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